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a second tube clamping member; and (d) means for hingeable movement of the second tube clamping member with respect to the first tube clamping member such that the second tube clamping member is movable between a closed clamping position, in which the tube is kept clamped between the first and second tube clamping members with the first tube clamping member extending under the tube, and an open position, in which the tube clamping means can freely receive the tube, without movement of the first tube clamping member relative to the first positioning means, the assembly further comprising securing means for detachably securing the assembly around the patient's head, said securing means comprising second positioning means for connecting the securing means to the first positioning means to facilitate positioning of the tube clamping means.

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Claim 56. (new) The assembly according to claim 55, wherein the first positioning means comprises a positioning plate which is substantially transverse to the first and second tube clamping members and is integrally formed with the first clamping member.

Claim 57. (new) The assembly according to claim 55, wherein the second positioning means comprises an occipital strap and a plurality of flexible, detachable attachment straps that extend between the occipital strap and the first positioning means, the occipital strap comprising slots for the attachment straps, the second positioning means comprising means for adjusting the attachment straps as to length whereby the attachment straps can be secured to themselves on both sides of the patient's head

with the tube fixed to the patient's head.

Claim 58. (new) The assembly according to claim 57, wherein the first positioning means comprises a positioning plate which is substantially transverse to the first and tube clamping members and which is integrally formed with the first tube clamping member, the attachment straps being connected to the positioning plate.

Claim 59. (new) The assembly according to claim 57, wherein the means for adjusting the attachment straps as to length comprises velcro.

Claim 60. (new) The assembly according to claim 56, wherein each of the attachment straps is connected to the plate at a plurality of locations and has a recess between the plurality of locations.

Claim 61. (new) The assembly according to claim 57, wherein the occipital strap comprises means for stiffening the slots.

Claim 62. (new) The assembly according to claim 61, wherein the means for stiffening comprises a rod extending along a side of the slot.

Claim 63. (new) The assembly according to claim 57, wherein the slots are disposed at a level with corners of a jaw of the patient with the assembly fixing the tube to the patient's mouth.

Claim 64. (new) The assembly according to claim 57, wherein the occipital strap is accommodated in a cap for placement over the patient's head.

Claim 65. (new) The assembly according to claim 64, wherein the cap comprises recesses for the patient's ears.

Claim 66. (new) The assembly according to claim 64, wherein the cap extends over the patient's head with the assembly fixing the tube to the patient's mouth, the cap comprising means for attachment of care or monitor lines at a front or upper side thereof.

Claim 67. (new) The assembly according to claim 55, wherein the means for hingeable movement provides for hingeable movement of the second tube clamping member about an axis that is substantially parallel to the tube with the tube disposed in the tube clamping means.

Claim 68. (new) The assembly according to claim 67, wherein each of the first and second tube clamping members comprises a half oval ring, the means for hingeable movement comprising a hinge, the half oval ring of each of the first and second tube clamping members being connected to each other by the hinge.

Claim 69. (new) The assembly according to claim 55, comprising catching means for securing the first and second tube clamping members to each other with the second

Fig 1
cont'd

tube clamping member in the closed clamping position.

Claim 70. (new) The assembly according to claim 55, wherein each of the first and second tube clamping members comprises a protrusion that protrudes inwardly for fixing the tube.

Claim 71. (new) The assembly according to claim 56, wherein the positioning plate comprises a slot for the tube.

Claim 72. (new) The assembly according to claim 55, wherein the first positioning means comprises a plurality of slots for attachment straps of the second positioning means.

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Claim 73. (new) The assembly according to claim 72, wherein the slots are vertically aligned. *not like P1*

Claim 74. (new) The assembly according to claim 56, wherein the first positioning means comprises a plurality of slots for attachment straps of the second positioning means, four of the slots being disposed in the plate in a rectangular configuration.

Claim 75. (new) The assembly according to claim 56, wherein the positioning plate conforms to the patient's face.

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Claim 76. (new) The assembly according to claim 56, wherein the positioning plate comprises a bite member at a rear portion thereof for positioning between teeth of the patient.

Claim 77. (new) The assembly according to claim 55, wherein the first tube clamping member comprises a continuous recess that, at least at an outer end of the first tube clamping member, extends over an entire cross-section of the first tube clamping member, whereby to accommodate a pilot tube.

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Claim 78. (new) The assembly according to claim 76, wherein the first tube clamping member comprises a continuous recess that, at least at an outer end of the first tube clamping member, extends over an entire cross-section of the first tube clamping member, whereby to accommodate a pilot tube, the positioning plate and the bite member comprising recesses that are aligned with the continuous recess for the pilot tube, the recess in the bite member being continuous over an entire length and cross-section of the bite member.

Claim 79. (new) The assembly according to claim 76, wherein the bite member is substantially U-shape in cross-section.

Claim 80. (new) The assembly according to claim 76, wherein the bite member and the positioning plate comprise respective concave surfaces and edges at sides thereof.

Claim 81. (new) The assembly according to claim 55, wherein the tube clamping means comprises a synthetic material.

Claim 82. (new) The assembly according to claim 69, wherein the first and second tube clamping members collectively comprise snap finger and cam means for detachably snapping the second tube clamping member to the first tube clamping member with the first and second tube clamping members in the closed clamping position.

Claim 83. (new) The assembly according to claim 71, wherein the positioning plate is substantially U-shape.

Claim 84. (new) The assembly according to claim 55, wherein said first tube clamping member is integrally formed with the first positioning means whereby it maintains its position with respect to the first positioning means during movement of the second tube clamping member between said open and closed positions.

Claim 85. (new) A method for fixing a tube to the mouth of a patient comprising the steps of:

- (i) providing the assembly of claim 55; and
- (ii) clamping the tube in the tube clamping means, with the securing means secured to the patient's head and with the tube fixed to the patient's head, by moving the second tube clamping member between the open position and the closed clamping

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position with the first tube clamping member fixed to the first position means.

REMARKS

The Official Action of March 29, 2002 has been carefully considered and reconsideration of the application as amended is respectfully requested.

Claims 28-54 have been canceled and rewritten as new claims 55-83. The new claims contain the recitations from the canceled claims, but have been drafted to avoid the informalities noted in the paragraphs appearing on page 1 of the Official Action. The claims as rewritten are believed to be free of the aforementioned informalities and are otherwise believed to be sufficiently definite to satisfy the dictates of 35 USC 112, second paragraph. The claims as rewritten are also believed to define statutory subject matter in accordance with the provisions of 35 USC 101.

As rewritten, claim 55 more clearly distinguishes over the cited art by the recitation that the second tube clamping member is movable between a clamping position and a non-clamping position without movement of the first tube clamping member relative to the positioning plate. This arrangement is shown in Fig. 2 of the drawings and is described in the specification at page 9, last paragraph, wherein only one of the half oval rings is described as moveable. This arrangement is juxtaposed with the arrangement of the prior art wherein both clamping members are moved to clamp a tube (compare paragraph bridging pages 1 and 2 of the specification with the arrangement described in the paragraph bridging pages 2 and 3 and in the last

paragraph on page 9).

New claims 84 and 85 have been added more completely to define the subject matter which Applicant regards as the invention. The recitations in claim 84 draw support, for example, from the specification as filed at page 10, lines 29 and 30 and Fig 2. The recitations in claim 85 draw support, for example from the specification as filed at page 9, lines 21-24, and page 12, lines 5-10.

The Examiner has rejected the claims under 35 USC 102(b) as allegedly being anticipated by Nestor et al or under 35 USC 103(a) as allegedly being unpatentable over Nestor et al in view of Starr or Russo. Applicant respectfully traverses these rejections.

Nestor et al disclose an endotracheal tube holder comprising a plate and two semi-circular tube clamps or jaws 18, 10 that are hingedly connected to the plate. During closing of the holder, both jaws are moved, as is explained in the paragraph bridging pages 1 and 2 of the present specification . The drawbacks of the Nestor tube holder are also discussed there.

The holder according to claim 55 is distinct from the Nestor holder in that one (a first) of the tube clamping members is integral with the plate. In other words, it is rigidly connected to the plate. According to claim 55, this first clamping member is arranged to extend under the tube during use. As a result, the first clamping member

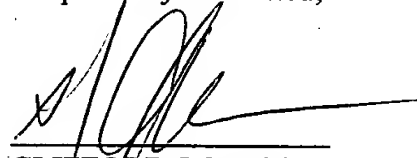
provides a stable and reliable support for the tube during placement of the tube and during closing clamping members. This arrangement of the changing members is not shown or suggested by the cited art.

With respect to the rejection of claims 30-33 and 37-39, Applicant notes that Starr shows a cap that is designed for holding a gas delivery mask, in contrast to holding and passing a tube. Starr does not disclose the use of additional straps extending between an occipital strap and the first positioning means. In the Starr arrangement, the occipital strap extends uninterruptedly to the mask. The use of intermediate straps, as recited in claim 57, has positive effects on the transfer of forces, in particular due to the slots and more particularly due to the strengthening rods extending along the slot (claim 62).

With respect to the rejections to claims 49 and 51-54, Applicant notes the Russo indeed shows a tube holder having a bite block. There is, however, to show or suggest a relatively stationary tube clamping member which itself is provided with a continuous recess extending, at least at the distal end of the (first) clamping member, over its entire cross-section (claim 78). As can be seen in figure 8 of Russo, the pilot tube can leave the bracket 25 only in an axial direction at the most distal end of the bracket. There would have been no motivation, absent the hindsight provided by the present specification, for a person of skill in the art to combine Nestor and Russo because the rigid and fixed bite members would give rise to tube alignment problems before and during closing the jaws of the Nestor device.

In view of the above, all claims as amended are believed patentably to distinguish over the cited art and the application is otherwise believed to be in condition for allowance. An early notice of allowance is earnestly solicited and is believed to be fully warranted.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'CJ Mass', is written over a horizontal line.

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